

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Tracy L. Bornman on 2 June 2009.

The application has been amended as follows:

1. Delete 1-13, 16, 20, and 26, 31-41.
2. In claim 19, line 3 before the term *reducing* **insert "and"**.
3. In claim 19, line 3 after *condition* **delete "and preventing a condition"**.
4. In claim 27, line 4 after *thereof*, **delete "precursors thereof,"**.
5. In claim 28, line 3 **delete "glycine betaine"** and **insert "a compound of formula** $(CH_3)_3N+(CH_2)_nCOO^-$ **with n being an integer of 1.**
6. In claim 29, line 3 **delete "glycine betaine"** and **insert "a compound of formula** $(CH_3)_3N+(CH_2)_nCOO^-$ **with n being an integer of 1.**
7. In claim 42, line 3, before *reducing* **insert "and"**.
8. In claim 42 line 3, after the term *condition* **delete " and preventing a condition,"**.

The following is the Examiner's statement of reasoning for allowance:

Reasons for allowance are supported by a lack of supportive evidence in the prior art (principally, Malumud et al. USPN 5,928,195) which discloses alkyl N-betaine in an embodiment

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which does not fairly teach the glycine betaine in a controlled release pharmaceutical system suitable for delivering after administration [...] of applicants' current invention.

Specifically, Malumud teach [...] a class of compounds comprising as a first component *an alkyl-N-betaine surfactant* and as a second compound an oxide selected from the group consisting of alkyl-N, N-dimethyl amine oxide, N-dihydroxyethylamine oxide, acylamino t-amine oxide and mixtures thereof, as disclosed in U.S. Pat. Nos. 4,107,328, 4,839,158 and 5,314,917, the disclosures of which are hereby incorporated herein by reference [...] (column 5, lines 37-43). In view of this disclosure, the teachings, methods, and modifications of Malumud are determined to be non-sufficient in obviousness over the limitations disclosed in the current claim set. Malumud by way of several other references incorporated *supra* within this paragraph teach *alkyl-N-betaine*, wherein the alkyl groups are C10 or higher. This modified chemical moiety would not have been obvious over $(CH_3)_3N^+(CH_2)_n COO^-$ with n being an integer of 1.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY E. BETTON whose telephone number is (571)272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TEB

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617